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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,894	07/05/2001	Kiyoshi Taniguchi	210100US0PCT	8683

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EXAMINER	
WRIGHT, SONYA N	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,894	TANIGUCHI ET AL.	
	Examiner	Art Unit	
	Sonya Wright	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10 and 18-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29, 30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 10 and 18-31 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29 and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

1) Nature of invention.

2) State of prior art.

3) Level of ordinary skill in the art.

4) Level of predictability in the art

5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7)Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention.

Claims 29 and 30 are drawn to a method for "treating, reducing, arresting, or alleviating matrix metalloproteinases (MMP) or tumor necrosis factor (TNF)-mediated disease".

2) State of the prior art.

The prior arts do not indicate what diseases the instant compound can be used to treat which involve matrix metalloproteinases (MMP) or tumor necrosis factor.

3) Level of ordinary skill in the art.

The level of skill in the art is high. Due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the compound of the claim 18 for treating all diseases pertaining to matrix metalloproteinases (MMP) or tumor necrosis factor (TNF).

Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 , states that " a patent is not a hunting license. It is not a reward for search , but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

4) Level of predictability in the art.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Hence, in the absence of a showing of treatment of all diseases related to matrix metalloproteinases (MMP) or tumor necrosis factor (TNF), one of skill in the art is unable to fully predict possible results from the administration of the compound of claim 18 due to the unpredictability of the art pertaining to matrix metalloproteinases (MMP) and tumor necrosis factor (TNF).

The nature of pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

5) Amount of direction and guidance provided by the inventor.

The specification provides little guidance regarding the use of the instant compound in matrix metalloproteinases (MMP) or tumor necrosis factor (TNF). Applicant provides background on the art of matrix metalloproteinases (MMP) and tumor necrosis factor (TNF) on pages 1 and 2. Applicant provides brief guidance on the

use of the instant compound in treating diseases related to matrix metalloproteinases (MMP) and tumor necrosis factor (TNF) on page 2 lines 20-30.

Applicant does not provide evidence that the instant compound is useful in treating all diseases related to matrix metalloproteinases (MMP) or tumor necrosis factor (TNF). The guidance is limited because various diseases related to matrix metalloproteinases (MMP) or tumor necrosis factor (TNF) have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol.

6) Existence of working examples.

The specification provides no examples of how the instant compound is used in treating diseases related to matrix metalloproteinases (MMP) or tumor necrosis factor (TNF).

7) Breadth of claims.

Claims 29 and 30 are extremely broad because they are drawn to all diseases related to matrix metalloproteinases (MMP) and tumor necrosis factor (TNF).

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

In view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage

in undue experimentation to test how the instant compound is useful in treating diseases related to matrix metalloproteinases (MMP) or tumor necrosis factor (TNF), with no assurance of success.

These rejections can be overcome by Applicant limiting claim 29 to "a method of treating" and by applicant listing in claim 29 which diseases related to matrix metalloproteinases (MMP) or tumor necrosis factor (TNF) can be treated by the instant compounds. Any diseases which are listed in claim 29 should be supported in the specification. It is suggested that Applicant cancel claim 30.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 is drawn to a process for manufacturing a medicament. However, it is unclear what is meant by the term "medicament". It appears that "medicament" is intended to mean "composition". Because a composition has been claimed in claim 27, it is suggested that Applicant cancel claim 31.

Claim Objections

Claim 10 is objected to for containing non-elected subject matter.

Allowable Subject Matter

Claims 18-28 are allowable over the prior art of record.

Response to Arguments

Applicant's arguments filed 9-29-03 have been fully considered and the Examiner agrees that claims 21-23 are amended to remove non-elected subject matter and that claims 24 and 26 are amended to correct informalities. Applicant's remarks filed 12-4-03 have been fully considered but they are not persuasive. In the remarks filed 12-4-03, Applicant argues that the Office has not established that the inventions of Groups I-XXII lack a single general inventive concept. Applicant argues that all of the alternative processes in claim 10 are of a similar nature and that all have the same activity, i.e. the production of the compound of claim 18. Applicant further argues that all of the reactions are related, with at least one of the reactants being a similar cyclic compound.

However, this is not found persuasive because it is pointed out that the restriction requirement is made under 35 U.S.C. 121. 35 U.S.C. 121 gives the Commissioner (Director) the authority to limit the examination of an application where two or more independent and distinct inventions are claimed to only one invention. In the instant case, each Group set forth in the restriction requirement is drawn to a different process which contains different reaction steps and conditions. A separate search would be required to search each Group with the reaction steps and conditions specific to each Group. More than one independent and distinct invention is claimed in this application and the Examiner has restricted (limited) the claimed subject matter accordingly. Thus, the requirement to restrict the claims in this application is predicated on the fact that the claimed subject matter involves more than one independent and distinct invention. Accordingly, the restriction is proper. Moreover, it would constitute a burden to extend

the search because separate search considerations would be involved in both the U.S. Patents and in the literature. The examination process following the search could easily result in different and thus burdensome considerations. Accordingly, the requirement to restrict is considered proper and is maintained. The search and examination of the application is directed to the subject matter of Group I, claims 10 and 18-31 wherein the process of claim 10 comprises reaction 1, only.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is

of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

Kamal Saeed
for Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

February 20, 2004